THE ASSOCIATION OF GOVERNING BOARDS OF UNIVERSITIES AND COLLEGES

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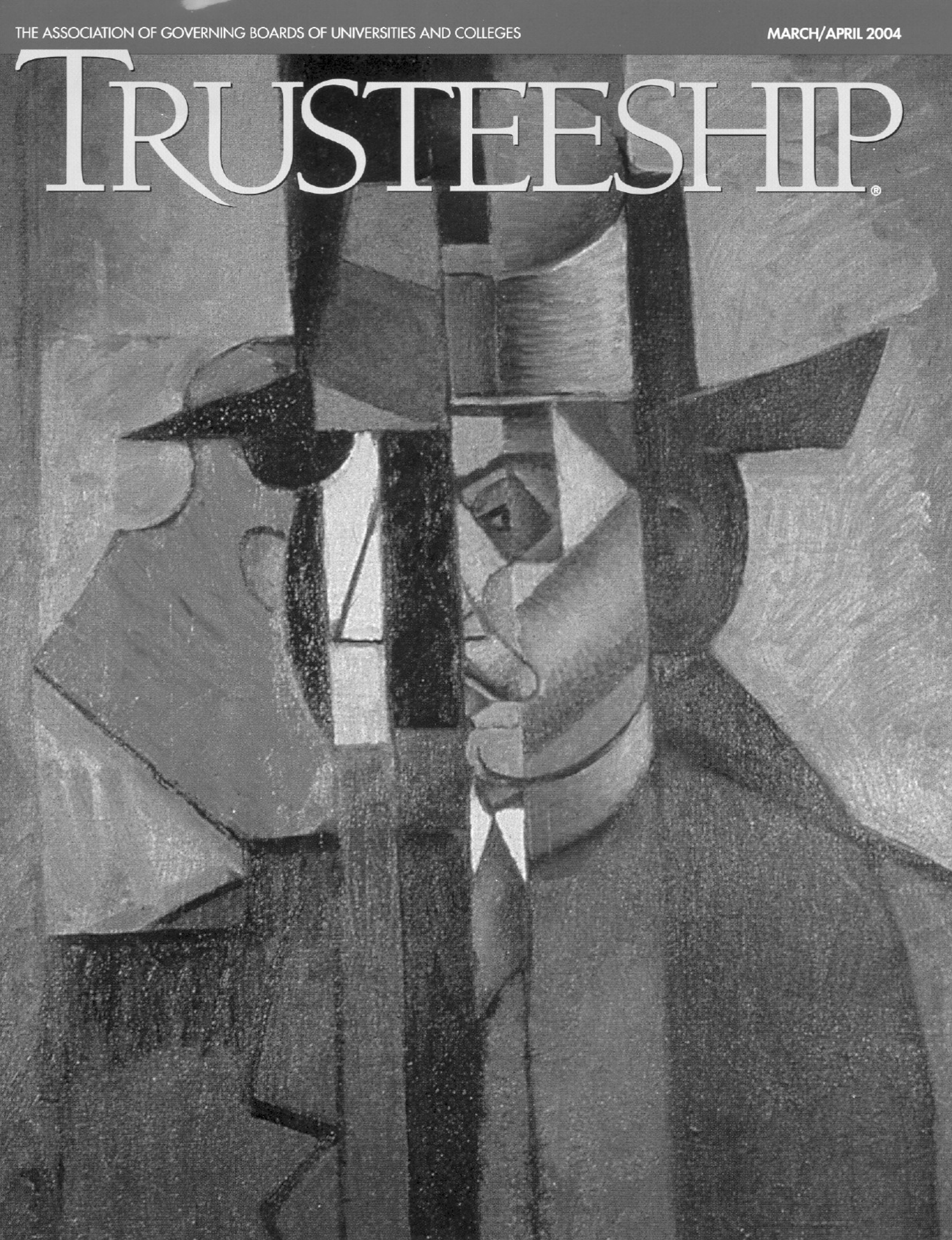


The Temptations of Corporate Funding

Scientific researchers on campus increasingly worry that commercial sponsorship skews conclusions and restricts data sharing. Boards can help balance conflicting interests.

RATHER THAN GIVE UP A PATENT CLAIM to a discovery in which he had played a key role, a student research assistant at the University of South Florida seven years ago chose a prison sentence.

The university had argued that it owned the intellectual property rights to any results growing out of his research. But the student most likely was practicing what universities have been preaching since the 1980s—namely, that knowledge and discovery are worth their weight in gold and that universities and their researchers should begin to share in the largesse that comes from privatizing and commercializing sponsored research.

In another case, medical doctors at UCLA removed an enlarged spleen from a Seattle land surveyor named John Moore, who had been diagnosed with leukemia. When Moore unexpectedly recovered from the leukemia, his clinicians discovered he had an unusual cell line that produced substances that aided his battle with the disease. They patented Moore's cells and sold the patent to a Swiss company for $15 million. Moore sued UCLA to gain some of the financial value from his body parts. The California Supreme Court ruled against Moore's claim to profit sharing, but ruled in his favor that physicians had an obligation to disclose their financial interests in his cells.

Both cases illustrate the evolving changes in the ethos of academic science that have made it increasingly difficult for universities to find a proper balance between commercialism and pure research.

• BY SHELDON KRIMSKY •

This country depends upon universities and nonprofit research institutes to provide disinterested science. Once universities take on a different role—one where the primary objective is to bring wealth to the institution by exploiting the commercial value of academic knowledge—they will slowly but inexorably lose their integrity and their virtue as the only remaining places where knowledge is pursued for its own sake and where individual investigators can be unconcerned that the outcome of their studies may have high financial stakes for their personal lives or their institution.

Without question, the most troubling aspect of the new commercialism embraced by America's nonprofit research institutions is its effect on the objectivity and quality of science. We are just now beginning to learn how having a financial stake in the subject matter of one's research can affect the design of a study and the interpretation of results.

Science eventually corrects itself, but in the intervening years, biased research may prove deadly to consumers in fields such as pharmacology, toxicology, environmental health, and food safety. Currently, private sources of fund-

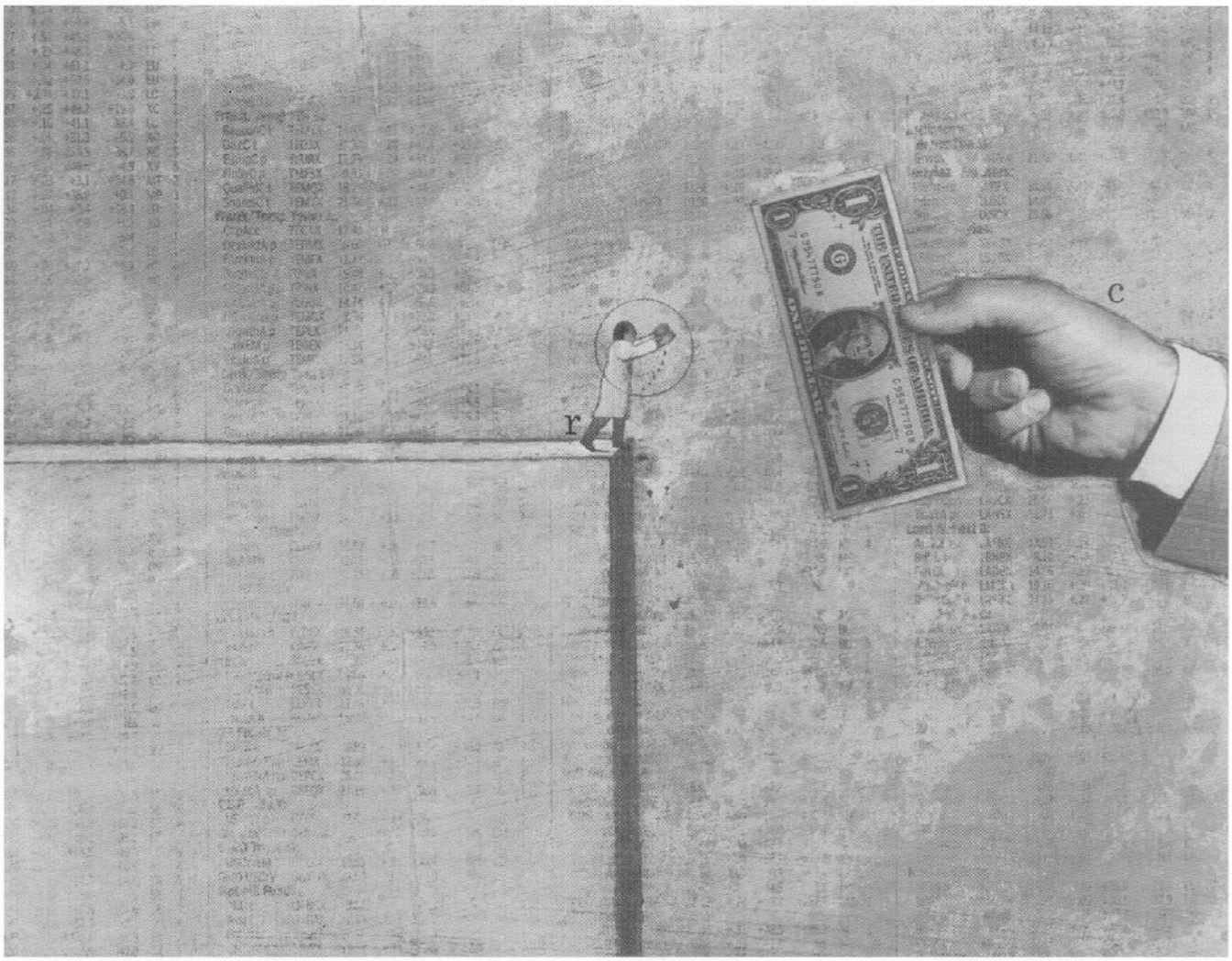
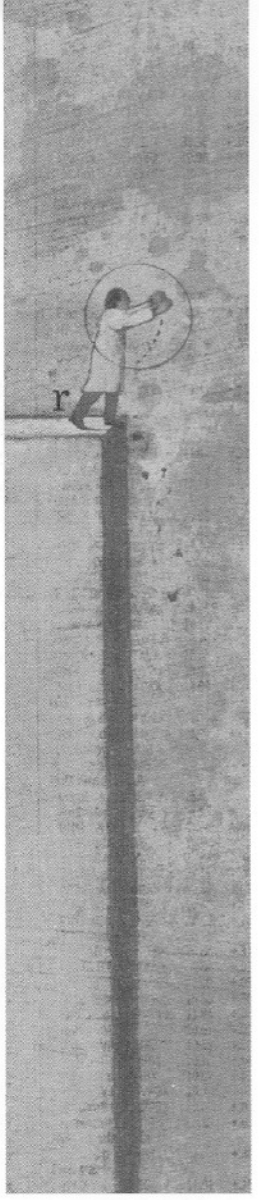


Illustration by Dave Lesh



ing comprise an average of about 7 percent of the entire research and development budget of universities. The critical decision for boards of trustees and all leaders at universities and nonprofit research institutes is where to set the balance in accepting privately funded research contracts.

How We Got Here. Four watershed events that took place in 1980 have contributed to transforming the way research universities view their role in society.

First, passage of the Bayh-Dole Act gave universities, small businesses, and nonprofit institutions the intellectual property rights to any inventions and discoveries that were derived from federally supported research. No longer would researchers or their institutions have to petition a federal agency to acquire the intellectual property rights to a discovery. Eventually, Bayh-Dole was extended to large businesses, providing an incentive for new cooperative arrangements between academia and industry.

Second, the Stevenson-Wydler Technology Innovation Act provided incentives for research collaboration between industry, government, and universities. Among the goals of the act were to stimulate cooperative technology development and transfer activities between universities and business, to provide them with greater potential for new income streams, and to allow collaborating companies to have privileged access to scientific breakthroughs.

Third, the Supreme Court ruled in *Diamond v. Chakrabarty* that a living organism could be patented. In the past, biological organisms such as yeast were patented as part of such processes as beer manufacturing. But the new ruling gave scientists the intellectual property rights over "anything under the sun made by man," including genetically modified plants, animals, microorganisms, and even genes and their protein products. Any scientist engaged in gene sequencing or genetic engineering of organisms was inevitably thrust into a new world of entrepreneurship.

Fourth, Harvard University in 1980 announced plans to invest in a commercial biotechnology company started by some of its faculty. Then-president Derek Bok eventually withdrew the proposal after a storm of negative reaction from faculty and alumni. Bok affirmed that "the preservation of academic values is a matter of paramount importance to the university, and owning shares of such a company would create a number of potential conflicts with those values." This short-lived initiative, however, inspired different outcomes in other universities, which did not see the conflicts so starkly. Twelve years later, Harvard dropped its reluctance to enter commerce as it invested in one of the largest venture-capital companies in the biotechnology field.

Many supporters argue that university entrepreneurship is a triple-win strategy. Businesses gain by signing lucrative research contracts and exclusive licensing agreements with universities. Academic institutions and their faculty gain by deriving new streams of revenue from institutional equity interests in faculty businesses, venture capital, patents, and licensing agreements. And the public gains by having new products and therapies that might not have been developed were it not for the collaborations.

Disturbing Reports. So, now that more than 100 universities have invested in for-profit companies, what are the problems? One downside to the growing commercialization of American universities is the rise in faculty and institutional conflicts of interest, a trend that erodes the appearance of objectivity.

This became evident in the tragic case of Jesse Gelsinger, who at age 17 volunteered to receive a treatment involving experimental gene therapy at the University of Pennsylvania Medical School. He died in the process in September 1999.

His father, Paul Gelsinger, even after his son's death, remained supportive of the medical community's efforts to find a cure for the genetic abnormality that afflicted Jesse, even though

Jesse was not expected to benefit from the procedure. But when Paul Gelsinger learned that both the university and the principal clinical investigator involved in his son's trial had equity interests in a company poised to exploit the financial benefits of the procedure, his support for the gene therapy group abruptly disappeared. The lawsuit he filed against the University of Pennsylvania cited the lack of informed consent and the absence of disclosure about conflict of interest among the complaints.

Universities are now struggling with whether to rewrite their institutional guidelines on clinical trials to require full disclosure about the financial ties that researchers have with companies that fund their studies.

What's more, there are ample tales in the literature of efforts by industry sponsors to control the publication of data produced by academic scientists when those data do not jibe with the commercial interests of the company. Some universities and nonprofit research institutes prohibit contracts that give sponsors control over experimental protocols, publication, or interpretation of data. But other universities have not proscribed the restrictive covenants of research agreements because they are more interested in the overhead value of science than in the protection of academic integrity.

More than a dozen papers have been published in the science literature that have demonstrated a "funding effect" in science. This means that, when matched with comparable studies funded by government and nonprofit institutes, industry-sponsored studies tend to support conclusions benefiting the industry.

Conflicts of interest among scientists have become commonplace in universities and in government. An investigation of 14 high-profile science and medical journals found that one-third of the articles published during the study year had first or last authors who had a financial interest in the subject matter of their article.

The Bayh-Dole Act has created unprecedented conflicts of interests among top government scientists as well. In December 2003, the

How A Board Can Monitor University-Industry Partnerships

Trustees should be aware of the changes in scientific norms taking place at their institutions in response to the lure of entrepreneurial science. They should be attuned to the compromises that the institution makes when it mixes pure science with pure profit.

A national meeting sponsored by the Pew Initiative on Food and Biotechnology on university-industry relationships held in 2002 resulted in a set of important questions that address the ethics of university-industry relationships. Here is a modified sample of those questions:

- Does the existence of a campus office of technology transfer or the opportunity to participate in a start-up company influence an academic scientist's research agenda?
- Does the university tenure and reward system affect a scientist's incentive to form an industry relationship?
- Do academic scientists with private funding and public funding have similar definitions of the public good?
- Does privately funded research restrict the ability of the scientist to exchange ideas, control the data, and publish the results in a timely manner?
- How prevalent are publication delays caused by intellectual property issues?
- What are the costs and revenues of university technology transfer operations and intellectual property transactions?
- What types of institutional conflicts of interest does the university have (including its portfolio effects on patenting licensing practices, equity holdings of faculty companies, or university-industry collaborations)?
- Does the university permit medical faculty who have conflicts of interest to participate in clinical trials?
- Does the university require full financial disclosure of medical faculty to the human subjects they attend to in clinical trials?

Los Angeles Times published a series on government scientists who act as paid consultants as well as an editorial that asked for repeal of the "most destructive portions" of the Bayh-Dole Act and restoration of the integrity of the National Institutes of Health. Sadly, the same corrosive effect on scientific integrity is occurring at America's elite universities.

Encouraging Changes. Rather than embrace disclosure as the universal and sole antidote to conflicts of interest, all of higher education should begin to adopt principles that prevent or prohibit the more egregious cases.

Some nonprofit institutions have begun to act more proactively. Leading medical journals have refused to publish editorials or review articles by scientists who have a financial interest in the subject. Privately funded research contracts are being vetted by some university lawyers to prevent any restrictions on academic freedom. A number of universities now prohibit any full-time faculty member from serving as a principal in a private company or accepting research funds from a company in which the scientist has substantial equity interests.

If the current trend at universities were to be generalized throughout other public and

How Boards Can Promote Science That Is in Everyone's Interest

That the academic world now is taking stock not only of scientific researchers who appear to shift their conclusions in favor of private funders, but also of university-industry partnerships that restrict research and withhold data is in some ways surprising and in other ways expected.

The situation is surprising because society holds physicians and scientific discoverers in high esteem. In my work, I meet countless scientists who tear away the curtains of ignorance and discover new truths for the sheer joy of doing it, not out of greed. And we all know that skeptical scientists challenge one another daily, eliminating every instance of error and untruth they can find and shunning the perpetrators.

The reported abuses are expected because we have seen corporate avarice and malfeasance erode our confidence in commercial institutions, and we concede that temptation, money, and fame may be an irresistibly corrupting combination.

How can governing boards respond to this problem?

Though universities have long been a source of new ideas that can be patented for commercial advantage, efficient companies and universities over the past two decades have joined to create a shortcut that some believe has turned campus discoverers into direct extensions of company research entities.

Spurred by enabling laws (Bayh-Dole, Stephenson-Wydler, and others), research universities justify their own pursuit of patents as "profit centers," often developing unrealistic beliefs about the valuation of their patents. The issue is whether the campus discoverers under these pressures will become short-horizon thinkers bent on creating new products and satisfying commercial contractors instead of patiently pursuing the important alternate problems and big breakthrough discoveries that over the long term serve both the university role and the commercial need.

Existing Safeguards. The Council of Scientific Society Presidents (*www.cssp.us*) represents about 150 scientific disciplines and 1.5 million scientists and science educators. Each discipline has a code of conduct that covers such arenas as conflict of interest, responsibility to expose misconduct, authorship of publications, data management, mentoring, peer review, humane treatment of animals, and responsibility to patients and human subjects.

Only a tiny fraction of this vast national science community has ever

BY MARTIN APPLE

nonprofit sectors, we would be eliminating an important firewall between those who produce knowledge and any stakeholders who have a financial interest in the applications of that knowledge.

Imagine for a moment if our judiciary system operated exclusively under a disclosure principle. Speaking before the court, a judge might disclose that he has an equity interest in the for-profit prison to which he is sentencing a convicted felon. How would we feel if the scientists who evaluated the human health risks of occupational toxins, second-hand smoke, mad cow disease, or global warming were all financially tethered to corporations that had much to gain from downplaying the hazards?

Surely, this is not the type of society we should encourage. Yet we must find ways to retain the integrity of our research institutions against the encroaching commercialization and conflict of interest. We must decide where we draw the line. ◆

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been involved with company-sponsored clinical studies or determinations of environmental health hazards. Aware of the risks and human biases, clinical researchers have developed evaluation and discovery processes that prevent many of the excesses that occasionally surface. A vast majority of researchers support, whenever feasible, use of the "gold standard" of double-blind patient studies. Each study is carried out after a federally funded local ethics review-board evaluation, followed by a rigorously peer-reviewed publication.

True, universities and commercial enterprises sometimes negotiate agreements questionably—for example, agreeing to keep ideas confidential or withhold publication. But the crux of the matter is whether they avoid noticing the bigger picture—the potential benefits of leaving the long-term curiosity and creativity of universities to flourish unfettered by vision-limiting constraints.

Neither party intends any harm; both see short-term benefits. However, as both parties jostle to take the lead in this dance, they may be creating an unintended erosion of even larger long-term benefits in order to satisfy current needs.

A New Social Contract. Hence, the governing boards of research universities need to proclaim that their institutions are and will remain the center for developing critical thinkers, for impartial and disinterested inquiry, and for open and rapid dissemination of new knowledge and ideas.

Boards can take a leadership role by first setting an example. They can endorse written conflict-of-interest policies and other codes of conduct for research (as many already have done) and then ask administrators to verify that such codes are widely communicated and adopted into practice on their campuses.

Boards can ask trenchant questions of research administrators. For example, are there ways to conduct selected areas of research so that the study and source of funding are double-blind to the researchers until the study is complete? Likewise, the board should reflect on whether it may be sending mixed signals and then blaming the confused error-makers for their own failures to both define and practice integrity. An enduring set of solutions may require university presidents and board chairs to sponsor creative campus forums to address the growing problems, tensions, and eroding trust being created in our field.

At the national level, groups of research vice presidents of universities and of commercial enterprises need to become personally engaged with one another and with the many leaders of the principal investigator community. The agenda of these discussions should be a candid discussion of one another's perspectives and concerns, resulting in a new social contract that will promote productive interaction for the long term.

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